

At page 70 line 4:

E2 *u*  
A. **ISOMIL® Soy Formula with Iron.**

At page 71 line 12:

E3 *u*  
B. **ISOMIL® DF Soy Formula For Diarrhea.**

At page 72 line 19:

E4 *u*  
C. **ISOMIL® SF Sucrose-Free Soy Formula With Iron.**

At page 73 lines 19-20:

E5  
D. **ISOMIL® 20 Soy Formula With Iron Ready to Feed,  
20 Cal/fl oz.**

At page 74 line 3:

E6  
-- E. **SIMILAC® Infant Formula**

At page 74 lines 24-28:

F. **SIMILAC NEOCARE® Premature Infant Formula With Iron**

Usage: For premature infants' special nutritional needs after hospital discharge.

E7  
SIMILAC NEOCARE® infant formula is a nutritionally complete formula developed to provide premature infants with extra calories, protein, vitamins and minerals needed to promote catch-up growth and support development.

At page 75 lines 18-19:

E<sup>8</sup> -- G. **SIMILAC NATURAL CARE® Low-Iron Human Milk Fortifier Ready To Use, 24 Cal/fl oz.**

At page 76 lines 7-12:

-- A. **ENSURE® Food Supplement**

E<sup>9</sup> Usage: ENSURE® food supplement is a low-residue liquid food designed primarily as an oral nutritional supplement to be used with or between meals or, in appropriate amounts, as a meal replacement. ENSURE® food supplement is lactose- and gluten-free, and is suitable for use in modified diets, including low-cholesterol diets. Although it is primarily an oral supplement, it can be fed by tube.

At page 77 lines 2-7:

E<sup>10</sup> Usage: ENSURE® BARS are complete, balanced nutrition for supplemental use between or with meals. They provide a delicious, nutrient-rich alternative to other snacks. ENSURE® BARS contain <1 g lactose/bar, and Chocolate Fudge Brownie flavor is gluten-free. (Honey Graham Crunch flavor contains gluten.)

At page 79 lines 2-8:

E<sup>11</sup> Usage: ENSURE® HIGH PROTEIN is a concentrate, high-protein liquid food designed for people who require additional calories, protein, vitamins, and minerals in their diets. It can be used as an oral nutritional supplement with or between meals or, in appropriate amounts, as a meal replacement. ENSURE® HIGH PROTEIN is lactose- and gluten-free, and is suitable for use by people recovering from general surgery or hip fractures and by patients at risk for pressure ulcers.

At page 80 lines 14-20:

E12 -- The level of fat in ENSURE® HIGH PROTEIN meets American Heart Association (AHA) guidelines. The 6 grams of fat in ENSURE® HIGH PROTEIN represent 24% of the total calories, with 2.6% of the fat being from saturated fatty acids and 7.9% from polyunsaturated fatty acids. These values are within the AHA guidelines of  $\leq 30\%$  of total calories from fat,  $\leq 10\%$  of the calories from saturated fatty acids and  $\leq 10\%$  of total calories from polyunsaturated fatty acids.

At page 80 lines 22-26:

E13 -- ENSURE® HIGH PROTEIN contains a combination of maltodextrin and sucrose. The mild sweetness and flavor variety (vanilla supreme, chocolate royal, wild berry, and banana), plus VARI-FLAVORS® Flavor Pacs food flavors in pecan, cherry, strawberry, lemon, and orange, help to prevent flavor fatigue and aid in patient compliance.

At page 81 lines 6-10:

E14 -- Usage: ENSURE® LIGHT is a low-fat liquid food designed for use as an oral nutritional supplement with or between meals. ENSURE® LIGHT is lactose- and gluten-free, and is suitable for use in modified diets, including low-cholesterol diets.

At page 82 lines 14-19:

E15 -- The level of fat in ENSURE® LIGHT meets American Heart Association (AHA) guidelines. The 3 grams of fat in ENSURE® LIGHT represent 13.5% of the total calories, with 1.4% of the fat being from saturated fatty acids and 2.6% from polyunsaturated fatty acids. These values are within the AHA guidelines of  $\leq 30\%$  of total calories from fat,  $\leq 10\%$  of the calories from saturated fatty acids and  $\leq 10\%$  of total calories from polyunsaturated fatty acids.

At page 82 lines 21-25:

E16 -- ENSURE® LIGHT contains a combination of maltodextrin and sucrose. The chocolate flavor contains corn syrup as well. The mild sweetness and flavor variety (French vanilla, chocolate supreme, strawberry swirl), plus VARI-FLAVORS® Flavor Pacs food flavors in pecan, cherry, strawberry, lemon, and 25 orange, help to prevent flavor fatigue and aid in patient compliance.

At page 83 lines 6-7:

E17 -- An 8-fl-oz serving of ENSURE® LIGHT provides at least 25% of the RDIs for 24 key vitamins and minerals.

At page 83 lines 11-17:

**E18 -- E. ENSURE PLUS® Liquid Nutritive Preparation**

Usage: ENSURE PLUS® liquid nutritive preparation is a high-calorie, low-residue liquid food for use when extra calories and nutrients, but a normal concentration of protein, are needed. It is designed primarily as an oral nutritional supplement to be used with or between meals or, in appropriate amounts, as a meal replacement. ENSURE PLUS® liquid nutritive preparation is lactose- and gluten-free. Although it is primarily an oral nutritional supplement, it can be fed by tube.

At page 84 lines 18-22:

E19 -- ENSURE PLUS® liquid nutritive preparation contains a combination of maltodextrin and sucrose. The mild sweetness and flavor variety (vanilla, chocolate, strawberry, coffee, butter pecan, and eggnog), plus VARI-FLAVORS® Flavor Pacs food flavors in pecan, cherry, strawberry, lemon, and orange, help to prevent flavor fatigue and aid in patient compliance.

At page 85 lines 4-5:

E20 -- An 8-fl-oz serving of ENSURE PLUS® liquid nutritive preparation provides at least 15% of the RDIs for 25 key Vitamins and minerals.

At page 85 lines 10-15:

-- **F. ENSURE PLUS® HN Liquid Nutritive Preparation**

E21 Usage: ENSURE PLUS® HN liquid nutritive preparation is a nutritionally complete high-calorie, high-nitrogen liquid food designed for people with higher calorie and protein needs or limited volume tolerance. It may be used for oral supplementation or for total nutritional support by tube. ENSURE PLUS® HN liquid nutritive preparation is lactose- and gluten-free.

At page 86 lines 13-16:

E22 -- Usage: ENSURE® POWDER (reconstituted with water) is a low-residue liquid food designed primarily as an oral nutritional supplement to be used with or between meals. ENSURE® POWDER is lactose- and gluten-free, and is suitable for use in modified diets, including low-cholesterol diets.

At page 87 lines 19-22:

E23 -- ENSURE® POWDER contains a combination of corn syrup, maltodextrin, and sucrose. The mild sweetness of ENSURE® POWDER, plus VARI-FLAVORS® Flavor Pacs food flavors in pecan, cherry, strawberry, lemon, and orange, helps to prevent flavor fatigue and aid in patient compliance.

At page 88 lines 2-5:

E24 -- Usage: ENSURE® PUDDING is a nutrient-dense supplement providing balanced nutrition in a nonliquid form to be used with or between meals. It is appropriate for consistency-modified diets (e.g., soft, pureed, or full liquid) or for people with swallowing impairments. ENSURE® PUDDING is gluten-free.

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At page 89 lines 5-8:

E<sup>25</sup> -- ENSURE® PUDDING contains a combination of sucrose and modified food starch.  
The mild sweetness and flavor variety (vanilla, chocolate, butterscotch, and tapioca) help prevent flavor fatigue. The product contains 9.2 grams of lactose per serving.

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At page 89 lines 18-25:

E<sup>26</sup> -- **I. ENSURE® WITH FIBER**  
Usage: ENSURE® WITH FIBER is a fiber-containing, nutritionally complete liquid food designed for people who can benefit from increased dietary fiber and nutrients. ENSURE® WITH FIBER is suitable for people who do not require a low-residue diet. It can be fed orally or by tube, and can be used as a nutritional supplement to a regular diet or, in appropriate amounts, as a meal replacement. ENSURE® WITH FIBER is lactose- and gluten-free, and is suitable for use in modified diets, including low-cholesterol diets.

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At page 91 lines 7-13:

E<sup>27</sup> -- The level of fat in ENSURE® WITH FIBER meets American Heart Association (AHA) guidelines. The 6 grams of fat in ENSURE® WITH FIBER represent 22% of the total calories, with 2.01% of the fat being from saturated fatty acids and 6.7% from polyunsaturated fatty acids. These values are within the AHA guidelines of  $\leq 30\%$  of total calories from fat,  $\leq 10\%$  of the calories from saturated fatty acids and  $\leq 10\%$  of total calories from polyunsaturated fatty acids.

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At page 91 lines 15-18:

E<sup>28</sup> -- ENSURE® WITH FIBER contains a combination of maltodextrin and sucrose. The mild sweetness and flavor variety (vanilla, chocolate, and butter pecan), plus VARI-

E28 FLAVORS® Flavor Pacs food flavors in pecan, cherry, strawberry, lemon, and orange, help to prevent flavor fatigue and aid in patient compliance.

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At page 92 lines 3-5:

E29 -- The fiber blend used in ENSURE® WITH FIBER consists of oat fiber and soy polysaccharide. This blend results in approximately 4 grams of total dietary fiber per 8-fl-oz can. The ratio of insoluble to soluble fiber is 95:5.

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At page 92 lines 9-14:

-- **J. OXEPA® Nutritional Product**

E30 OXEPA® is a low-carbohydrate, calorically dense enteral nutritional product designed for the dietary management of patients with or at risk for ARDS. It has a unique combination of ingredients, including a patented oil blend containing eicosapentaenoic acid (EPA from fish oil),  $\gamma$ -linolenic acid (GLA from borage oil), and elevated antioxidant levels.

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At page 92 line 18:

- E31
- The distribution of Calories in OXEPA® nutritional product is shown in Table 7.
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The table at page 92 line 19:

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**Table 7. Caloric Distribution of OXEPA® Nutritional Product**

	per 8 fl oz.	per liter	% of Cal
Calories	355	1,500	---
Fat (g)	22.2	93.7	55.2
Carbohydrate (g)	25	105.5	28.1
Protein (g)	14.8	62.5	16.7
Water (g)	186	785	---

At page 92 line 21:

- OXEPA® nutritional product contains 22.2 g of fat per 8-fl oz serving (93.7 g/L).

At page 92 lines 22-24:

- The fat source is a oil blend of 31.8% canola oil, 25% medium-chain triglycerides (MCTs), 20% borage oil, 20% fish oil, and 3.2 % soy lecithin. The typical fatty acid profile of OXEPA® nutritional product is shown in Table 8.

At page 93 lines 1-2:

- OXEPA® nutritional product provides a balanced amount of polyunsaturated, monounsaturated, and saturated fatty acids, as shown in Table 10.

At page 93 lines 6-7:

- The various fatty acid components of OXEPA® nutritional product can be substituted



E<sup>35</sup> and/or supplemented with the PUFAs of this invention.

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The table at page 93 line 9:

E<sup>36</sup>

Table 9. Fat Profile of OXEPA® Nutritional Product	
% of total calories from fat	55.2
Polyunsaturated fatty acids	31.44 g/L
Monounsaturated fatty acids	25.53 g/L
Saturated fatty acids	32.38 g/L
n-6 to n-3 ratio	1.75:1
Cholesterol	9.49 mg/8 fl oz 40.1 mg/L

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At page 94 lines 6-10:

- E<sup>37</sup>
- The high-fat and low-carbohydrate content of OXEPA® nutritional product is designed to minimize carbon dioxide (CO<sub>2</sub>) production. High CO<sub>2</sub> levels can complicate weaning in ventilator-dependent patients. The low level of carbohydrate also may be useful for those patients who have developed stress-induced hyperglycemia.

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At page 94 line 11:

- E<sup>38</sup>
- OXEPA® nutritional product is lactose-free.

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At page 94 lines 12-20:

E39 Dietary carbohydrate, the amino acids from protein, and the glycerol moiety of fats can be converted to glucose within the body. Throughout this process, the carbohydrate requirements of glucose-dependent tissues (such as the central nervous system and red blood cells) are met. However, a diet free of carbohydrates can lead to ketosis, excessive catabolism of tissue protein, and loss of fluid and electrolytes. These effects can be prevented by daily ingestion of 50 to 100 g of digestible carbohydrate, if caloric intake is adequate. The carbohydrate level in OXEPA® nutritional product is also sufficient to minimize gluconeogenesis, if energy needs are being met.

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At page 94 line 22:

- E40
- OXEPA® nutritional product contains 14.8 g of protein per 8-fl-oz serving (62.5 g/L).

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At page 94 lines 24-28:

- E41
- OXEPA® nutritional product provides enough protein to promote anabolism and the maintenance of lean body mass without precipitating respiratory problems. High protein intakes are a concern in patients with respiratory insufficiency. Although protein has little effect on CO<sub>2</sub> production, a high protein diet will increase ventilatory drive.

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At page 95 lines 1-2:

- E42
- The protein sources of OXEPA® nutritional product are 86.8% sodium caseinate and 13.2% calcium caseinate.